

## REMARKS

Claims 24-53 are currently pending in this application. Claims 24-27, 30-31, 38-39 and 44-52 stand withdrawn. Claims 28, 32, 33, 35, 36, 40 and 53 are amended herein. Upon entry of this response with amendments, claims 24-53 will remain pending. Support for amended claims 28, 32, 33, 35, 36, 40 and 53 can be found throughout the application as originally filed, *inter alia*, on page 5, lines 28-29, on page 9, lines 15-34, and on page 13, lines 15-17.

### Rejections

#### *Rejections under 35 U.S.C. § 112, 1<sup>st</sup> Paragraph*

Claims 28-29, 32-37, 40-43 and 53 were rejected under 35 U.S.C. § 112, 1<sup>st</sup> paragraph, as allegedly failing to comply with the enablement requirement. More specifically, the Office Action states that the specification does not reasonably provide enablement for any and all enzymes which are capable of converting a compound into a substrate for the galactose oxidase. *See* Office Action, Page 2, lines 19-21. According to the Office Action, the specification is not enabled for all enzymes capable of converting a compound into a substrate for galactose oxidase, and it would be an undue burden for one of ordinary skill in the art to test any and all enzymes to determine whether the enzyme possesses this function.

Applicants respectfully disagree and traverse this rejection.

It is well established under 35 U.S.C. §112 ¶ 1, that “[t]he test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.” (*United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1986)). The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976), MPEP § 2164.01. The factors to be considered in determining whether a disclosure would require undue experimentation include: “(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative

skill of those in the art, (7) the predictability of the art, and (8) the breadth of the claims.” *In re Wands*, 858 F.2d 731, 773 (1988).

As an initial matter, Applicants appreciate the Examiner’s recognition that the specification is enabling for at least galactanase. However, Applicants respectfully submit that the specification provides enablement for additional second component enzymes useful for generating oxidizable substrates for galactose oxidase. The specification teaches a number of particularly useful second component enzymes for the generation of oxidizable substrates for galactose oxidase, including a cellulase, a hemicellulase, a pentosanase, a xylanase, an arabinofuranisodase, a galactanase, a mannanase and a  $\beta$ -galactosidase. *See* specification, page 9, lines 31-34 and page 10, lines 4-5. Furthermore, the specification teaches that other supplementary components can be added to the composition, such as cellulases, starch degrading enzymes such as amylases, pullulases, proteases and oxidoreductases. *See* specification, page 10, lines 1-7.

In addition, the working examples of the specification provide teachings showing that the incubation of pectolytic enzyme 2524-70 (P70), a crude ferment of *Aspergillus niger* containing several enzyme activities, such as pectolytic activity, with arabinogalactan yielded oxidizable substrates for galactose oxidase. *See* Example 1.2, pages 17-18. In addition, the specification provides at least one assay system, the ABTS assay described on pages 18-19, whereby one of skill in the art is readily able to determine whether a potential substrate for galactose oxidase yields hydrogen peroxide when incubated in the presence of galactose oxidase and peroxidase, the hydrogen peroxide serving as an indicator of galactose oxidase activity. Accordingly, one skilled in the art is enabled to determine whether D-galactose has been produced from the starting compound when incubated with a second component enzyme for the production of oxidizable substrates for galactose oxidase.

Accordingly, Applicants submit that they have enabled one of skill in the art to select particularly preferred enzymes useful for generating oxidizable substrates for galactose oxidase, as well as taught at least one assay system useful to identify combinations of compound and second component enzyme(s) that will yield D-galactose, an oxidizable substrate for galactose oxidase. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 28-29, 32-37, 40-43 and 53 under 35 U.S.C. § 112, 1<sup>st</sup> paragraph, as allegedly failing to comply with the enablement requirement.

*Rejections under 35 U.S.C. § 112, 2<sup>nd</sup> Paragraph*

Claims 28-29, 32-37, 40-43 and 53 were rejected under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph, as indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More specifically, the phrase “an enzyme which is capable of converting a compound into a substrate for the galactose oxidase” is alleged to be confusing.

Applicants respectfully disagree and traverse this rejection.

Applicants submit that the term “compound” as used in the instant application is not indefinite or confusing. The term “compound” refers to a component of the composition that is capable of being degraded, hydrolysed or otherwise converted to substrates such as galactan, a galactose oligomer or a galactose dimer that can be used as a substrate by galactose oxidase.

As pointed out in Applicants’ specification, the natural content of galactose or other oxidizable substrates for galactose oxidase is very low. Thus, “[p]ractical use of that enzyme in a flour based dough is therefore not possible without providing in the dough a sufficient amount of oxidizable substrates for the enzyme.” *See* specification, page 5, lines 6-9. Therefore, oxidizable substrates for galactose oxidase should be included with flour dough compositions in order to use this enzyme with flour dough. The present invention addresses this problem by providing a composition comprising a galactose oxidase as a first component, and as additional components an oxidizable substrate for galactose oxidase and an enzyme capable of degrading, hydrolysing or otherwise converting a native compound into the oxidizable substrate for galactose oxidase. Therefore, the claimed composition includes an oxidizable substrate for galactose oxidase and/or an enzyme capable of converting a native substrate into an oxidizable substrate for galactose oxidase. *See* specification, page 7, lines 7-10.

The specification states that suitable substrates for galactose oxidase include free molecules of D-galactose and other substrates that contain galactose moieties present in a position and a configuration readily accessed and oxidized by galactose oxidase. *See* specification, page 7. Examples of specific substrates include a galactan, a galactose oligomer or a galactose dimer. The compound that is capable of being converted by the second component enzyme may or may not act as a direct substrate for galactose oxidase. However, in certain situations, it is necessary to hydrolyze or degrade the compound by the

second component enzyme to generate suitable substrates for galactose oxidase, such as a galactan, a galactose oligomer or a galactose dimer.

Thus, the compound can be any compound that is capable of being treated by the second enzyme in order to generate substrates such as a galactan, a galactose oligomer or a galactose dimer that can be used as an oxidizable substrate for galactose oxidase. Non-limiting examples of compounds useful to generate oxidizable substrate for galactose oxidase include gums, such as guar gum and locust bean gum, as well as chemically-linked galactose units, hemicellulose, pentosans or xylans. *See* specification, page 9, lines 19-26. Accordingly, Applicants submit that the term “compound” as used in the specification and as recited in the claims is definite.

Applicants also submit that the term “conversion” as was used in the claims is definite. For example, the specification on pages 8-9 discusses that “the galactose oxidase-containing composition comprises as a second component an enzyme which is capable of *converting* a galactose-containing compound which is not in itself a substrate for the galactose oxidase into a substrate for the galactose oxidase.” *See* specification, page 8, lines 24-29 (emphasis added). The specification continues by stating that “ a suitable second component enzyme is an enzyme which can hydrolyse or otherwise degrade galactose-containing compounds or structural components [t]hereof to provide an oxidizable substrate for galactose oxidase.” *See* specification, page 9, lines 27-31. The discussion of convertible galactose-containing compounds is further supported by the biochemical reaction as described in the schematic drawing located on page 9. Accordingly, Applicants submit that the term “conversion” is definite and fully supported by the specification as originally filed. Notwithstanding the remarks provided *supra*, Applicants have amended claim 33 to recite “...hydrolysing or otherwise degrading...,” to expedite prosecution.

All of the other rejected claims ultimately depend from claim 33 and therefore incorporate the elements of claim 33 as well. Accordingly, in light of the remarks and claim amendments provided herein, Applicants submit that the rejected claims, as amended, are definite and comply with the requirements of 35 U.S.C. § 112, 2<sup>nd</sup> paragraph. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 28-29, 32-37, 40-43 and 53 under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph.

*Rejections under 35 U.S.C. § 103*

Claims 28-29, 32-37, 40-43 and 53 were rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Beggs *et al.* (U.S. Patent 5,490,988), Goers *et al.* (U.S. Patent 5,156,840) or Goers *et al.* (U.S. Patent 4,867,973) in view of International Publication No. WO 93/25239, Jung *et al.* (U.S. Patent 5,478,576), Aoda *et al.* (U.S. Patent 4,344,968), Wirth *et al.* (U.S. Patent 3,832,340), Morishita *et al.* (U.S. Patent 4,609,640), or Baichwal *et al.* (U.S. Patent 5,662,933). The Office Action states that the aforementioned references disclose that galactose oxidase and galactans are known to be used in pharmaceutical compositions, and that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The Office Action concludes that the invention is obvious since the two components are both known in the art to be used for the same purpose, namely pharmaceutical purposes. See Office Action, page 5.

Applicants respectfully disagree and traverse this rejection.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met.

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one skilled in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure.

In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991), In re Wilson, 424 F.2d 1382 (CCPA 1970), MPEP §§ 2142, 2143.

Beggs *et al.*, Goers *et al.* ('840 patent) or Goers *et al.* ('973 patent) taken in view of WO 93/25239, Jung *et al.*, Aoda *et al.*, Wirth *et al.*, Morishita *et al.*, or Baichwal *et al.* do not satisfy these basic criteria.

Applicant submits that Beggs *et al.*, Goers *et al.* ('840 patent) or Goers *et al.* ('973 patent) taken in view of WO 93/25239, Jung *et al.*, Aoda *et al.*, Wirth *et al.*, Morishita *et al.*, or Baichwal *et al.*, fail to teach all of the claim elements. Neither Beggs *et al.*, Goers *et al.* ('840 patent), Goers *et al.* ('973 patent), WO 93/25239, Jung *et al.*, Aoda *et al.*, Wirth *et al.*, Morishita *et al.*, or Baichwal *et al.*, alone or in combination, teach or suggest a flour dough

improving composition. As a result, not all of the claim elements are taught or suggested by the cited references. For at least this reason, Applicants submit that the claimed subject matter is not obvious in light of the cited references, and respectfully request reconsideration and withdrawal of the rejection of claims 28-29, 32-37 40-43 and 53 under 35 U.S.C. § 103 as allegedly unpatentable.

## CONCLUSION

Applicants submit that all claims under consideration are in condition for allowance for all the reasons discussed above. Early notification of a favorable consideration and allowance of all claims are respectfully requested.


In the event any outstanding issues remain, Applicants would appreciate the courtesy of a telephone call to their undersigned Counsel to resolve such issues and place the application in condition for allowance.

Respectfully submitted,

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